

REVISIÓN DE SEIS ENSAYOS

## Celebrex es más peligroso para los pacientes con riesgo cardiovascular

- Según un estudio, los médicos sólo deberían recetarles dosis bajas de este fármaco

Actualizado martes 15/04/2008 14:40 ([CET](#))

CRISTINA DE MARTOS

MADRID.- La 'superaspirina' fabricada por Pfizer, Celebrex, cuenta entre sus efectos adversos con el aumento de los problemas de corazón en las personas que la toman. Esta complicación está relacionada con la dosis administrada y es mayor en aquellos individuos con predisposición a sufrir estas patologías, según una revisión de varios estudios.

El trabajo, publicado en la revista 'Circulation', fue presentado en una reunión científica del Colegio de Cardiología de Estados Unidos. Los resultados sugieren que el daño potencial de Celebrex afecta sobre todo a los pacientes más 'sensibles' a las complicaciones cardiovasculares.

"Estos datos deberían dar **cierta tranquilidad** a la hora de recetar celecoxib [principio activo de este fármaco] a enfermos con un perfil de riesgo cardiovascular bajo", declaró Scott Solomon, investigador jefe del estudio financiado por el Instituto Nacional del Cáncer, según informa Reuters.

Celebrex pertenece a la familia de los inhibidores de la COX-2, un grupo de medicamentos que desembarcó en el mercado como alternativa menos agresiva para el estómago a los demás analgésicos y antiinflamatorios. Pero pronto empezaron a aparecer los problemas que culminaron en la retirada de [Vioxx](#) (fabricado por Merck and Co.) en 2004 y de Bextra, de Pfizer.

El celecoxib es la única 'superaspirina' que aún se comercializa en Estados Unidos, pero la FDA, que regula los fármacos en este país, está muy pendiente de su trayectoria. De hecho, **Celebrex tiene pendiente la inclusión en su prospecto de una 'caja negra'**, una advertencia acerca del riesgo que su consumo supone para la salud cardiovascular.

Solomon y sus colegas, algunos de los cuales han recibido en alguna ocasión financiación de Pfizer, analizaron los datos de seis ensayos con celecoxib en los que tomaron parte 7.950 pacientes. Los participantes tomaban 400 miligramos al día, 200 mg dos veces al día o dos dosis diarias de 400 mg del fármaco o de un placebo.

Un análisis inicial mostró que el riesgo de muerte por patologías cardiovasculares, infarto, ictus, fallo cardiaco o formación de coágulos era mayor con la toma de dos dosis de 400 mg e inferior para la dosis única de 400 mg. Los que tomaban esta misma cantidad pero racionada en dos presentaban un peligro intermedio.

Cuando los investigadores introdujeron en la ecuación el perfil de riesgo cardiovascular de los pacientes antes de iniciar este tratamiento se percataron de que aquellos con peor pronóstico previo eran los que estaban más amenazados por la aparición de estas complicaciones con dosis altas de Celebrex.

Según los autores, ante un paciente con factores de riesgo cardiovascular, **los médicos sólo**

**deberían recetarles dosis bajas de este fármaco.** Los resultados también deben tranquilizar a los facultativos cuando haya que tratar a alguien que no tenga esta característica, añaden.

Es importante señalar que en el tratamiento de la osteoartritis se suelen emplear 200 mg diarios de celecoxib, inferior a lo estudiado. Sin embargo, para la artritis reumatoide, el dolor agudo, la dismenorrea o la adenomatosis familiar se administran dosis iguales o superiores a los 400 mg.



[el mundo.es](http://el mundo.es)

**SALUD**

LOS PROBLEMAS DE LAS 'SUPERASPIRINAS'

## Dudas sobre Celebrex

Actualizado miércoles 10/05/2006 15:55 (CET)

Apenas tres meses después de que, en septiembre de 2004, se retirase del mercado el moderno analgésico Vioxx debido a su riesgo coronario, un ensayo clínico sugería que otro fármaco de esa misma familia (Celebrex) podría tener problemas cardiovasculares a dosis elevadas. Desde entonces, la seguridad de los antiinflamatorios, clásicos y modernos, ha estado en el punto de mira. Lea las informaciones al respecto.

- [Celecoxib ya no necesita visado \(25.10.2006\)](#)
- [Vuelven los anuncios de Celebrex en EEUU \(10.05.2006\)](#)
- [Un gran estudio evaluará la seguridad de los antiinflamatorios \(14.12.2005\)](#)
- [La Agencia Europea zanja el debate sobre la seguridad de los COX-2 \(28.06.2005\)](#)
- [Nuevas evidencias de que todos los antiinflamatorios tienen riesgo cardiovascular \(17.06.2005\)](#)
- [Se matizan los riesgos de los antiinflamatorios \(11.06.2005\)](#)
- [Los reumatólogos españoles debaten la seguridad de los COX-2 \(23.05.2005\)](#)
- [Los antiinflamatorios advertirán de sus potenciales peligros \(07.04.2005\)](#)
- [Las autoridades de EEUU también limitan el uso de los COX-2 \(22.02.2005\)](#)
- [Las autoridades europeas restringen el uso de los COX-2 \(18.02.2005\)](#)
- ['New England' cuestiona la utilidad de todos los COX-2 \(16.02.2005\)](#)
- [Pfizer retrasa la venta en Europa de un fármaco similar a Celebrex \(21.01.2005\)](#)
- [La Agencia Europea del Medicamento revisa los COX-2 \(19.01.2005\)](#)
- [Llamada a la calma tras los datos de los riesgos de varios antiinflamatorios \(15.01.2005\)](#)
- [Inhibidores de la Cox2, un castillo de naipes que se desmorona \(29.12.2004\)](#)
- [Dieciocho antiinflamatorios a examen \(29.12.2004\)](#)
- [La agencia europea acelera la revisión de las 'superaspirinas' \(23.12.2004\)](#)
- [Pfizer suspende en EEUU la publicidad de Celebrex \(20.12.2004\)](#)
- [Un estudio detecta riesgo coronario en usuarios de Celebrex \(17.12.2004\)](#)
- [Pfizer se la juega para demostrar que su 'coxib' no daña el corazón \(23.10.2004\)](#)
- [La alternativa de Pfizer se beneficia de la retirada de Vioxx \(06.10.2004\)](#)
- [La agencia europea del medicamento evaluará los productos similares a Vioxx](#)

# BEXTRA

[HOME](#) | [BEXTRA RESOURCES](#) | [CONTACT AN ATTORNEY](#) | [FUND YOUR CASE TODAY](#) | [FREQUENTLY ASKED QUESTIONS](#)

## Bextra Class Action Lawsuits and Claims

[Bextra lawyers](#) are ready to help. If you can establish that you have been injured as a result of using Bextra, you may have the right to monetary damages including reimbursement for medical expenses, any loss of income, pain and suffering, and even punitive damages if special circumstances can be proven. Do you have a case? No matter what state you live in, click on a panel from the left or right side of this page. Pharmaceutical litigation (defect drug litigation) is governed by federal laws, so no matter where you live any of these featured LawInfo Qualified lead counsel **Bextra attorneys** can help you with your claim.

## Did you know?

Two recent small studies run by Pfizer (the manufacturer of Bextra) have shown that heart bypass surgery patients taking Bextra (valdecoxib), an anti-inflammatory that serves a similar function as the recently withdrawn drug Vioxx, had a higher risk of stroke and heart attack. **Recent evidence suggests that Bextra increased the risk of stroke and heart attack when it was given to very high-risk patients who had undergone coronary bypass surgery.** Bextra is also being linked to Stevens Johnson Syndrome, a rare inflammatory skin disorder that can be life-threatening - up to 27 percent of those affected incur long term eye damage or vision loss, and up to 15 percent die.

Bextra has only been studied in arthritis patients for up to a year. Doctors said it is too early to quantify the potential risk of Bextra or of Pfizer's other COX-2 inhibitor Celebrex as neither have tested for long enough. Pfizer said it is conducting longer term trials in arthritis patients. Serious safety concerns about the entire class of COX-2 inhibitors, including Bextra, have been raised due to the recent Vioxx recall.

Have you been taking Bextra? If so, you may have a claim for a lawsuit. **Contact a [Bextra attorney](#)** in your area now!

## Additonal Bextra Information

If you'd like more information regarding Bextra, including clinical studies and Food and Drug Administration (FDA) resources, please see the following Bextra links:

- [Bextra Heart Attack](#)
- [Bextra Side Effects](#)
- [Bextra Class Action](#)
- [Bextra Lawsuit](#)

## Lawyers Ready to Take Your Bextra Case

On this site, you will find law firms staffed with **qualified and experienced [Bextra attorneys](#)** who specialize in cases such as these. These **bextra lawyers** are Lead Counsel members, which means,

among other things, that they have been practicing for several years, dedicate themselves to this type of legal issue, and are in good standing with their local bar associations.

Plaintiffs in cases such as these typically seek to recover damages for medical costs, lost wages and pain and suffering. Click through on any of the firms listed on both sides of this page, and feel free to ask questions regarding your particular situation. The [Bextra lawyers](#) featured here will handle your inquiry quickly and responsibly. If the attorney feels that further discussion and investigation is warranted, he or she will guide you through the process and provide you with quality representation when necessary.

If you have suffered a personal injury as a result of taking the drug Bextra, now is the time to assert your rights. **Contact one of our experienced [Bextra lawyers](#) now to file your claim.**

## Bextra News

- [FDA issues warnings about more pain relievers](#)
- [FDA urges Pfizer to pull Bextra from shelves, issues Celebrex, Vioxx warning](#)
- [New Studies About Bextra - Bextra Lawyers May Be Able to Help](#)

[More News](#)

> [Back to Top](#)

## COX-2 Selective (includes Bextra, Celebrex, and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

- [Home](#) >
- [Drugs](#) >
- [Drug Safety and Availability](#) >
- [Postmarket Drug Safety Information for Patients and Providers](#)

### Section Contents Menu

- [Drug Safety and Availability](#)
- [Postmarket Drug Safety Information for Patients and Providers](#)
  - [Index to Drug-Specific Information](#)
  - [Approved Risk Evaluation and Mitigation Strategies \(REMS\)](#)
  - [Postmarketing Safety Evaluation of New Molecular Entities: Final Report](#)
  - [Drug Safety Communications](#)
- [Drug Safety Information for Healthcare Professionals](#)

[4/7/2005] The Food and Drug Administration (FDA) has issued supplemental request letters to sponsors of all non-steroidal anti-inflammatory drugs (NSAID) requesting that they make labeling changes to their products. These letters include recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. The Celebrex labeling will, in addition to the general labeling that will apply to all NSAIDs, also contain safety data from long-term treatment trials with celecoxib.

Manufacturers of **non-prescription** (over-the-counter) NSAIDs are being asked to revise their labeling to provide more specific information about the potential CV and GI risks of their individual products and remind patients of the limited dose and duration of treatment of these products in accordance with the package instructions

In making these decisions, the Center for Drug Evaluation and Research (CDER) considered the risk/benefit profile for each of the drugs. Also considered was;

- review of the regulatory histories and new drug application (NDA) databases of the various NSAIDs,
- FDA and sponsor background documents prepared for the [joint Advisory Committee meeting of FDA's Arthritis and Drug Safety and Risk Management Advisory Committees](#)<sup>1</sup>, held February 16-18, 2005,
- all materials and data submitted by other stakeholders to the Advisory Committee

meeting,  
presentations made at the joint meeting

- the specific votes and recommendations made by the joint Committee.

Further information regarding the decisions being announced and specific details regarding the individual products can be found within the documents posted to this Web page.

- [Public Health Advisory](#)<sup>2</sup> (4/7/2005)
- [FDA Press Release - FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-Inflammatory Drugs \(NSAIDs\)](#)<sup>3</sup> (4/7/2005)
- [Questions and Answers](#)<sup>4</sup>
- [Decision Memo - Analysis and Recommendations for Agency Action - COX-2 Selective and Non-selective NSAIDs \(PDF - 143KB\)](#)<sup>5</sup> (issued 4/6/2005, posted 4/15/2005)
- [COX-2 Selective Drugs](#)<sup>6</sup> (including Bextra, Celebrex, and Vioxx)
- Prescription NSAID Products (6/15/2005)
  - [Supplemental Request Letter \(PDF - 45KB\)](#)<sup>7</sup>
  - [Labeling Template \(PDF - 50KB\)](#)<sup>8</sup>
  - [COX-2 Medication Guide \(PDF - 115KB\)](#)<sup>9</sup>
- Over-the-Counter NSAID Products
  - **New July 15, 2005.** The agency has issued new supplemental labeling request letters for OTC NSAID products. The Agency received comments from industry regarding the June 14th supplemental labeling request letter and labeling template. Upon completion of our review of the comments, the Agency has decided to make revisions to the OTC labeling template and issue a new supplemental labeling request letter.
    - [Revised Supplemental Request Letter and Labeling Template \(PDF - 192KB\)](#)<sup>10</sup> (7/18/2005)
    - [Supplemental Request Letter and Labeling Template \(PDF - 183KB\)](#)<sup>11</sup> (6/15/2005)
  - COX-2 Selective Non-steroidal Anti-inflammatory Drugs (NSAIDs) and Prescription and Over-the-Counter (OTC) Non-selective NSAIDs Approved Under New Drug Application (NDA) Abbreviated New Drug Application (ANDA) [Table of Drug Products](#)

## COX-2 Selective Drugs

### **Bextra (valdecoxib)**

On April 7, 2005, the Food and Drug Administration (FDA) asked Pfizer to voluntarily remove Bextra (valdecoxib) from the market.

#### **Background Information**

- [Healthcare Professional Sheet](#)<sup>12</sup> (4/7/2005)
- [Questions and Answers: Strengthening Warnings on Bextra](#)<sup>13</sup> (12/9/2004)
- [Public Health Advisory: Non-Steroidal Anti-Inflammatory Drug Products](#)<sup>14</sup> (NSAIDs) (12/23/2004)

[Back to Top](#)

### **Celebrex (celecoxib)**

## Background Information

- [Healthcare Professional Sheet](#)<sup>15</sup> (4/7/2005)
- **FDA Alert: 3/2005.** Based on emerging information, including preliminary reports from one of several long term National Institutes of Health (NIH) prevention studies, the risk of cardiovascular events (composite endpoint including MI, CVA and death) may be increased in patients receiving Celebrex. FDA will be analyzing all available information from these studies to determine whether additional regulatory action is needed.
  - [Regulatory History of Celebrex from Drugs@FDA](#)<sup>16</sup>
  - [FDA Statement on the Halting of a Clinical Trial of the Cox-2 Inhibitor Celebrex](#)<sup>17</sup> (12/17/2004)
  - [Public Health Advisory: Non-Steroidal Anti-Inflammatory Drug Products](#)<sup>18</sup> (NSAIDS) (12/23/2004)

[Back to Top](#)

## Vioxx (rofecoxib)

[9/30/2004] Merck & Co., Inc. announced a voluntary withdrawal of Vioxx (rofecoxib) from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events (including heart attack and stroke) in patients on Vioxx. Vioxx is a prescription COX-2 selective, non-steroidal anti-inflammatory drug (NSAID) that was approved by FDA in May 1999 for the relief of the signs and symptoms of osteoarthritis, for the management of acute pain in adults, and for the treatment of menstrual symptoms. Vioxx was later approved for the relief of the signs and symptoms of rheumatoid arthritis in adults and children.

## Background Information

- [Congressional Statement on Vioxx and Drug Safety](#)<sup>19</sup> (Posted 11/18/2004)
- Slide Presentation by Sandra Kweder, M.D., November 10, 2004 [[PowerPoint](#)<sup>20</sup>] (Posted 11/10/2004)
- [9/30/2004 Study Report \(PDF - 532KB\)](#)<sup>21</sup> (Posted 11/2/2004)
- [FDA Public Health Advisory: Safety of Vioxx](#)<sup>22</sup> (9/30/2004)
- [Vioxx \(rofecoxib\) Questions and Answers](#)<sup>23</sup> (9/30/2004)

## Other Prescription Non-selective NSAIDs

- [Healthcare Professional Sheet](#)<sup>24</sup> (4/7/2005)

[Back to Top](#)

**COX-2 Selective Non-steroidal Anti-inflammatory Drugs (NSAIDs) and Prescription and Over-the-Counter (OTC) Non-selective NSAIDs Approved Under New Drug Application (NDA) Abbreviated New Drug Application (ANDA)**

### COX-2 Selective NSAIDs

Chemical Name	Brand Name
Celecoxib	Celebrex



Valdecoxib	Bextra
Rofecoxib	Vioxx

<b>Non-selective NSAIDs</b>	
<b>Chemical Name</b>	<b>Brand Name</b>
Diclofenac	Cataflam, Voltaren, Arthrotec (combination with misoprostol)
Diflunisal	Dolobid
Etodolac	Lodine, Lodine XL
Fenoprofen	Nalfon, Nalfon 200
Flurbiprofen	Ansaid
Ibuprofen**	Motrin, Motrin IB, Motrin Migraine Pain, Advil, Advil Migraine Liqui-gels, Ibu-Tab 200, Medipren, Cap-Profen, Tab-Profen, Profen, Ibuprohm, Children's Elixsure *, Vicoprofen (combination with hydrocodone), Combunox (combination with oxycodone)
Indomethacin	Indocin, Indocin SR, Indo-Lemmon, Indomethegan
Ketoprofen**	Oruvail, Orudis, Actron
Ketorolac	Toradol
Mefenamic Acid	Ponstel
Meloxicam	Mobic
Nabumetone	Relafen
Naproxen**	Aleve, Naprosyn, Anaprox, Anaprox DS, EC-Naproxyn, Naprelan, Naprapac (copackaged with lansoprazole)
Oxaprozin	Daypro
Piroxicam	Feldene
Salsalate	Disalcid
Sulindac	Clinoril
Tolmetin	Tolectin, Tolectin DS, Tolectin 600

\*There are many OTC Combinations with ibuprofen: Advil Cold And Sinus, Advil Cold, Advil Allergy Sinus, Children's Advil Allergy Sinus, Ibuprohm Cold and Sinus, Sine-Aid IB, Children's Motrin Cold.

\*\*There are over-the-counter versions of these prescription medications.



-  
-

**Links on this page:**

1. <http://www.fda.gov/ohrms/dockets/ac/cder05.html#DrugSafetyRiskMgmt>
2. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm150314.htm>
3. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108427.htm>
4. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106148.htm>
5. <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106201.pdf>
6. <http://www.fda.gov/ssl/ucm103420.htm#COX2>
7. <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106210.pdf>
8. <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106230.pdf>
9. <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM106241.pdf>
10. <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106249.pdf>
11. <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106252.pdf>
12. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124649.htm>
13. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106255.htm>
14. <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm051900.htm>
15. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124655.htm>
16. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchTerm=celebrex&SearchType=BasicSearch>
17. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108384.htm>
18. <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm051900.htm>
19. <http://www.fda.gov/NewsEvents/Testimony/ucm113235.htm>
20. <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106877.ppt>
21. <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106880.pdf>
22. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106274.htm>
23. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106290.htm>
24. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm085282.htm>

Page Last Updated: 01/27/2010

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).